


EXHIBIT 177

 Abbott Laboratories Pharmaceutical Products Division (PPD)				
SUBJECT: Federal Health Care Program and Other Third Party Payor Requirements – United States – Reimbursement Information and Support		PROCEDURE NO: P2-04-01	ISSUE DATE: 10/25/2004	PAGE: 1 of 6
INITIATOR: Joe Fiske, Director – Pricing & Planning		DATE:	SUPERSEDES: New	EFFECTIVE BY DATE:
APPROVED: Robert Funck, PPD Division VP/Controller		DATE:		
APPROVED: Sujata Dayal, PPD Office of Ethics & Compliance		DATE:		
APPROVED: Clifford Berman, Senior Counsel		DATE:		

I. PURPOSE

This procedure establishes requirements to ensure that Reimbursement Information and Reimbursement Support relating to PPD Products is furnished to Customers consistent with the requirements of Federal Health Care Programs and state and federal laws relating to other third party health benefit programs (including but not limited to private insurance, employer group health plans, and other state or local programs) as set forth in OEC policy B2-04.

II. SCOPE

This Procedure is applicable to all employees of PPD, including PPD Pricing and Planning, PPD Managed Care, PPD Hospital Pharma and PPD Marketing, involved in providing reimbursement information and reimbursement support relating to PPD Products when operating within the United States or its territories. References to employees in this Procedure include agents.

III. DEFINITIONS

“Abbott Products” means products or services marketed, promoted, leased, sold, or otherwise distributed by Abbott.

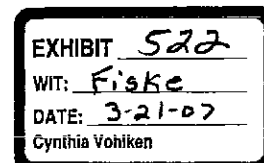
“Centralized Reimbursement Department” means any centralized location or department, approved by the Director, Corporate Reimbursement, established to provide Reimbursement Information and Support. The corporation or a division may have one or more Centralized Reimbursement Departments.

“Customer” means all health care professionals, institutions, providers, suppliers, wholesalers, distributors, patients, consumers, medical businesses, and their employees.

“Federal Health Care Programs” include any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly in whole or in part by the United States government, including but not limited to Medicare, Medicaid, Tricare, Department of Veterans Affairs programs, state CHIP programs, and block grant programs under titles V and XX of the Social Security Act, but not including the Federal Employee Health Benefits program.

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"PPD Products" means products or services marketed, promoted, leased, sold, or otherwise distributed by PPD.

"Reimbursement Communication Center" means a center (including but not limited to, toll-free call centers and websites), established to communicate information generated by the Centralized Reimbursement Department.

"Reimbursement Information" means information relating to the coverage, coding, or payment amounts for Abbott Products including any PPD Products, including but not limited to information on third party payor policies relating to coverage, coding or payment.

"Reimbursement Support" means assistance provided to a Customer regarding the submission or processing of a claim for an Abbott Product, including a PPD Product, related thereto, including but not limited to coverage investigations, claims filing, prior authorization, medical necessity determination, benefit denial investigation, or claims appeals.

IV. REQUIREMENTS

A. General –

PPD employees may provide Reimbursement Information and Reimbursement Support only in accordance with this PPD Operating Procedure and OEC Policy B2-04.

B. Reimbursement Information -

1. General. PPD employees may provide the types of Reimbursement Information specified below to Customers in accordance with the standards specified below, so long as:
 - a. PPD employees will undertake reasonable efforts to ensure that the information is current, accurate and complete, including a comprehensive review at least annually;
 - b. PPD employees shall advise the Customer that the Customer is ultimately responsible for determining the appropriate codes, coverage, and payment policies for individual patients; and
2. Coverage Information. PPD employees may inform Customers that a product is covered by a particular payor and provide copies of publicly available payor coverage policies furnished through or with the approval of the PPD Centralized Reimbursement Department.
3. Billing Codes. PPD employees may communicate billing codes (e.g., HCPCS, CPT, APC, DRG) applicable to PPD Products, if such codes are furnished through or with the approval of the PPD Centralized Reimbursement Department. Where feasible, the applicable payor coding policy should be provided or referenced.
4. Reimbursement/Payment.
 - a. General -
 - i. PPD employees may provide Reimbursement Information to Customers concerning payment amounts for PPD Products only in accordance with this operating procedure:
 - (a) No PPD employee should provide reimbursement amounts to Customers either verbally or in writing, except that written information based on

publicly available payment amounts may be distributed if it is approved for such distribution by the Centralized Reimbursement Department. In addition, Customers should be referred to an approved Reimbursement Communication Center to obtain payment amount information.

- (b) Information must be publicly available (e.g., CMS listing or published payor fee schedule).
- (c) The PPD Centralized Reimbursement Department shall verify, at least annually, payment amount information to be provided to Customers.
- ii. PPD employees may provide information with respect to current published catalog prices and contract prices for products.
- iii. Under no circumstances may PPD employees guarantee third-party coverage or payment for PPD Products, or reimburse Customers for claims that are denied by third party payors.
- iv. PPD employees shall not create their own reimbursement aids ("home grown" materials).
- b. Average Wholesale Price Information (AWP) -
 - i. No PPD employee shall provide Average Wholesale Price information to Customers and must refer all queries to outside drug databases, except that helpines approved by a Centralized Reimbursement Department may communicate AWP information that is included in an actual drug database listing or, subject to approved PPD Procedures, PPD managed care sales employees may provide AWP information directly to managed care Customers.
 - ii. Rebates may be calculated based upon AWP's as reported by First Data Bank. PPD Pricing & Planning may use the calculation of such rebate and may provide such AWP information to the customer as part of the supporting documentation for the rebate calculation referencing the data source for AWP.
 - iii. Information provided by PPD to drug databases should communicate only WAC (wholesale acquisition cost or list price) and not AWP.
- c. Margin Information and Reimbursement Modeling
 - i. PPD employees may not use or provide Customers with tools to enable reimbursement modeling which may be used to determine the margin between acquisition costs and reimbursement amounts ("spread"). Examples of such tools include reimbursement calculators, charts and spreadsheets.
 - ii. PPD employees may not provide reimbursement margin, spread, or other information about profitability to Customers, and must decline to respond to requests for such information. For example, a PPD employee may not inform a Customer that they will receive greater reimbursement by using a PPD Product over a competitor's product.
- d. Beneficiary Copayment Information
 - i. PPD employees may not provide information to health care providers/Customers concerning beneficiary co-payments in connection with Federal Health Care Programs.

- ii. PPD employees shall not encourage health care providers/Customers to waive beneficiary co-pays
- e. Usual and Customary Charge Levels/Cost Reporting
 - i. PPD employees shall not provide information regarding or recommend usual and customary charge levels or other amounts that providers should bill to third parties.
 - ii. PPD employees shall not recommend or suggest cost centers to which the costs for Abbott Products should be assigned, allocated, or apportioned in cost reports submitted to third parties.

5. Medical Necessity and Other Federal Health Care Program Information.

- a. No information may be provided to physicians or health care providers, or their staff or agents, that encourages specific diagnostic coding to obtain payment. No PPD employee may encourage or make a medical necessity determination on behalf of an individual patient. PPD employees may provide publicly available Medical Necessity, National Program Memoranda, Medicare Transmittals, National Coverage Decisions, Medical Review Policies supplied by a Centralized Reimbursement Department, including Local Medical Review Policies (or "LMRPs") developed by the Medicare contractors or other publicly available individual information, which describe the medical conditions for which a product may be covered. All material must be dated.
- b. PPD employees may not provide or suggest or confirm ICD-9 or other diagnostic codes to document medical necessity for patients, except as permitted on an exceptions basis by PPD operating procedures.

6. Review of Sales and Marketing Materials.

- a. All sales and marketing materials, including training or presentation materials, containing Reimbursement Information must be reviewed and approved by the Director, Corporate Reimbursement and an appropriate Senior Counsel or Division Vice President from the Legal Division, in addition to being reviewed under the med/reg process established by PPD operating procedures.
- b. All helplines (external, internal, or other companies' through co-marketing) that provide reimbursement services must have scripts approved by the Director, Corporate Reimbursement and an appropriate Senior Counsel or Division Vice President from the Legal Division, in addition to being reviewed under the med/reg process established by PPD operating procedures. Scripts should be updated annually.

C. Reimbursement Support –

- 1. PPD may provide Reimbursement Support to Customers only through Abbott helplines approved by the Director, Corporate Reimbursement, in accordance with the standards set forth below and applicable division operating procedures.

Engagements of third parties to provide Reimbursement Support must be pursuant to written agreements approved by an appropriate Senior Counsel or Division Vice President from the Legal Division. The written agreement shall contain specific guidelines for support to be provided and such guidelines shall be consistent with this procedure.

2. All Reimbursement Support must be provided consistent with the restrictions on the use and disclosure of protected health information under the Health Insurance Portability and Accountability Act ("HIPAA") and similar state laws.
3. PPD may contact third party payors to investigate coverage and benefit parameters for PPD Products, may furnish Customers with payor-required prior authorization forms, may provide medical literature in support of coverage of particular uses of PPD Products consistent with FDA regulations, may make inquiries regarding the status of prior authorization and medical necessity requests, and may provide other Reimbursement Support activities approved by the Director, Corporate Reimbursement and an appropriate Senior Counsel or Division Vice President from the Legal Division, all in accordance with division operating procedures.

D. Lobbying/Advocacy Efforts -

Designated Abbott representatives, including PPD employees if so designated, pursuant to applicable Corporate and/or Division policies and/or operating procedures, may provide information about products and payment policies to government officials (including administrators of Federal Health Care Programs), Customers, patients, competitors and others for purposes of lobbying or public advocacy. This information may include product characteristics, the connection between product characteristics and payment policies, as well as recommendations about payment policies, amounts and procedures.

E. Exceptions -

Exceptions to this Operating Procedure may only be granted with the approval of (1) the President of PPD, (2) the PPD Division Ethics and Compliance Officer, and (3) a Senior Counsel or DVP from the Legal Division.

V. **RESPONSIBILITIES**

1. Divisions/Businesses - PPD

To monitor compliance with this procedure and together with the Office of Ethics and Compliance and the Legal Division to develop and implement training programs addressing these requirements. To operate such programs in compliance with this procedure and OEC Policy B2-04.

2. Corporate Internal Audit -

To adopt and implement auditing protocols which address compliance with the specific requirements of this procedure.

3. Office of Ethics and Compliance – PPD

To assist divisions in identifying and verifying current, accurate, and complete coding information for PPD Products that may be disclosed to Customers.

To monitor and promote compliance with this procedure and to promote consistency between the divisions.

To review and approve any revisions to this procedure.

To monitor training activities.

To provide ethics and compliance guidance interpreting this procedure and matters covered by this procedure.

4. Legal Division -

An appropriate Senior Counsel or Division Vice President from the Legal Division to review and approve any revisions to this procedure.

To provide legal guidance interpreting this procedure and matters covered by this procedure.

VI. REFERENCES

Related Documents:

- Federal Health Care Program Requirements- United States

VII. DESCRIPTION OF CHANGE

New Policy